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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/711,681

09/30/2004

Robert T. Striker

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09/03/2009

QUARLES & BRADY LLP

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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

NOTIFICATION DATE

DELIVERY MODE

09/03/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	10/711,681	STRIKER ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,11-13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of applicants' amendments and remarks submitted May 12, 2009 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6, 11-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korant (WO00/21565), in view of Gunnarsdottir et al. (J. Pharmal Exp. Therapeutics, IDS) .

3. Korant teaches a method of treating hepatitis C infection comprising administering to the patient a cytotoxic agent, such as 6-mercaptopurine. See, particularly, page 4, lines 15-24, page 6, line 17. Korant teaches a preferred dosage range of 0.1 mg to 30 mg/kg of body weight. See, page 17, lines 3-12.

4. Korant does not teach expressly an example for employment of 6-mercaptopurine for treating hepatitis C infection, or the employment of the particular prodrug of 6-mercaptopurine.

5. However, Gunnarsdottir et al. disclose that the AVTP (the compound I) is a known prodrug of 6-mercaptopurine, with less bone marrow toxicity. See, particularly, the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ 6-mercaptopurine, or its prodrugs, such as compound I for treatment of hepatitis C.

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A person of ordinary skill in the art would have been motivated to employ 6-mercaptopurine, or its prodrugs, such as compound I for treatment of hepatitis C because 6-mercaptopurine is known to be useful for treatment of hepatitis C and a known prodrug would have reasonably been expected to be similarly useful as the drug itself. One of ordinary skill in the art would have been further motivated to use compound I because of its less bone marrow toxicity. Further, a method known to be useful for treatment of hepatitis C infection would have been expected to be useful for treatment of any patient with Hepatitis C, including the host of a liver transplant patient. Claims 5 and 6 merely recite a biological passway of the prodrug and do not carry any limitation to any step of claimed method.

6. Claims 1-6, 11-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stuyver (US 2005/0049220), in view of Gunnarsdottir et al. (J. Pharmal Exp. Therapeutics, IDS) .

7. Stuyver teaches a method of treatment of hepatitis C infection comprising administering to the patient an antimetabolite, such as 6-mercaptopurine, or azathioprine. See, particularly, the abstract, paragraphs [0100]. The amount of antimetabolite may be in the range of 100 mg to 1500 mg per day [0071].

8. Stuyver does not teach expressly the employment of the particular prodrug of 6-mercaptopurine.

9. However, Gunnarsdottir et al. disclose that the AVTP (the compound I) is a known prodrug of 6-mercaptopurine, with less bone marrow toxicity. See, particularly, the abstract.

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Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to employ a prodrugs of 6-mercaptopurine, such as compound I for treatment of hepatitis C.

A person of ordinary skill in the art would have been motivated to employ a prodrugs of 6-mercaptopurine, such as compound I for treatment of hepatitis C because a known prodrug would have reasonably been expected to be similarly useful as the drug itself. One of ordinary skill in the art would have been further motivated to use compound I because of its less bone marrow toxicity. Further, a method known to be useful for treatment of hepatitis C infection would have been expected to be useful for treatment of any patient with Hepatitis C, including the host of a liver transplant patient. Claims 5 and 6 merely recite a biological passway of the prodrug and do not carry any limitation to any step of claimed method.

Response to the Arguments

Applicants' amendments and remarks submitted May 12, 2009 have been fully considered, but are not persuasive with respect to the rejections set forth above.

10. Applicants contend that the claimed invention is not obvious over the prior art because Korant reference and Stuyer reference do not teach the inhibition of viral replication as herein set forth. The arguments are not probative. It is noted that the instant claims are directed to affecting a biochemical pathway with an old and well known compounds. The argument that such claims are not directed to the old and well known ultimate utility (treating HCV) for the compounds, e.g., 6-mercaptopurine, or its prodrug AVTP, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to *In re Swinehart*, (169 USPQ 226 at 229)

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where the Court of Customs and Patent Appeals stated “is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.” In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

11. As to the rejections over Korant et al., in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., using the agent alone) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. In response to applicant's argument that the cited prior art does not teach the inhibition of viral replication, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Applicants' attention is further directed to *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1397 (2007), where the court states: "In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103."

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The prior art need not suggest combining references for the same reason that a patent applicant combined them. In instant case, the primary references teach the employment of cytotoxic, or antimetabolites for the treatment of viral infection, particularly, HCV infection. One of ordinary skill in the art would have been motivated to use the prodrug of 6-MP, such as AVTP, in such method because it reduce the side effect. Note the cytotoxicity is the feature the prior art used against HCV infection. Therefore, Gunnarsdottir reference teaches that AVTP is more cytotoxic and provide further motivation to one of ordinary skill in the art for using it. Gunnarsdottir reference teaches AVTP (the compound I) is a known prodrug of 6-mercaptopurine, with less bone marrow toxicity. Therefore, one of ordinary skill in the art would have reasonably expected that AVTP as therapeutic agent will have less side effect.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617